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# Hepatitis C Policy Discussion

**Purpose of the Discussion:**
The purpose of this policy discussion is to evaluate necessary changes to the current prior authorization [PA] criteria if the Oregon Health Authority determines it has the fiscal capacity to expand access to all patients with chronic hepatitis C without fibrosis restrictions.

**Recommendation:**

- Approve updated prior authorization (PA) criteria (**Appendix 1**).

**Background:**
Chronic hepatitis C (CHC) infection is the leading cause of complications from chronic liver disease, including cirrhosis, liver failure, and hepatocellular carcinoma (HCC). It is also the leading indication for liver transplantation in the Western world.[1] About 10-20% of people with CHC develop cirrhosis (8-16% of all people infected with HCV), and the time to progress to cirrhosis varies at an average of 40 years.[1] Progression of fibrosis is commonly categorized using METAVIR staging (F0 to F4) with higher scores indicating more severe fibrosis.

The Oregon Drug Use Review/Pharmacy & Therapeutics (P&T) Committee initially prioritized treatment for the fee-for-service population to patients in greatest need of treatment.[1] Limited real-world experience and data, consideration for the number of patients waiting for treatment, limited provider expertise, and the limited number of alternative treatment options in cases of treatment resistance and patient comorbidities all played a role in prioritizing treatment.[1] As more treatment options become available, real world experience increases, and the community standard evolves, the P&T Committee has expanded treatment in a step-wise fashion to patients with less severe disease. Current drug policies in place approve treatment for patients with fibrosis Metavir stage 2 or greater, or patients with extrahepatic manifestations or HIV at any stage of fibrosis, and patients in the setting of solid organ transplant (see **Appendix 1**).

**References:**

1. Drug Use Research & Management Program. Class Update with New Drug Evaluations: Hepatitis C Direct-Acting Antivirals. September 2017; http://www.orpdl.org/durm/meetings/meetingdocs/2017_09_28/archives/2017_09_28_HepatitisC_ClassUpdate.pdf. Accessed August 24, 2018.

**Appendix 1.** Proposed Prior Authorization Criteria

# Hepatitis C Direct-Acting Antivirals

**Goals:**

Approve use of cost-effective treatments supported by the medical evidence.
Provide consistent patient evaluations across all hepatitis C treatments.
Ensure appropriate patient selection based on disease severity, genotype, and patient comorbidities.

**Length of Authorization:**

- 8-16 weeks

**Requires PA:**

All direct-acting antivirals for treatment of Hepatitis C

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for treatment of chronic Hepatitis C infection (defined by persistent HCV RNA detection for ≥6 months for newly diagnosed patients, fibrosis testing indicating advanced fibrosis OR clinical evidence of cirrhosis)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is expected survival from non-HCV-associated morbidities more than 1 year? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 4. Has <u>all</u> of the following pre-treatment testing been documented:<br>a. Genotype testing in past 3 years;<br>b. Baseline HCV RNA level in past 6 months;<br>c. Current HIV status of patient<br>d. Current HBV status of patient<br>e. Pregnancy test in past 30 days for a woman of child-bearing age; <u>and</u><br>f. History of previous HCV treatment and outcome?<br><br>Note: Direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis. Prior to treatment with a DAA, all patients should be tested for HBsAG, HBsAb, and HBcAB status. | **Yes:** Record results of each test and go to #5<br><br>Note: If the patient has HIV or HBV co-infection, it is highly recommended that a specialist be consulted prior to treatment.<br><br>Currently treatment is not recommended during pregnancy due to lack of safety and efficacy data | **No**: Pass to RPh. Request updated testing. |
| 5. Which regimen is requested? | Document and go to #6 | |
| ~~6. Does the patient have HIV coinfection and is under treatment by a specialist with experience in HIV?~~<br><br>~~Note: persons with HIV/HCV coinfection are at risk for rapidly progressing fibrosis~~ | ~~**Yes:** Go to #10~~ | ~~**No:** Go to #7~~ |

| Approval Criteria | | |
|---|---|---|
| ~~7.~~6. Does the patient have:<br>a) ~~A biopsy, imaging test (transient elastography [FibroScan®], acoustic radiation force impulse imaging [ARFI], or shear wave elastography [SWE]) to indicate portal fibrosis with septa (METAVIR F2) advanced fibrosis (METAVIR F3) or cirrhosis (METAVIR F4);~~<br><br>**~~OR~~**<br><br>Clinical, radiologic or laboratory evidence of complications of cirrhosis (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma, esophageal varices)? | **Yes:** Go to #~~7~~10<br><br>~~Note: Other imaging and blood tests are not recommended based on evidence of poor sensitivity and specificity compared to liver biopsy. However, if imaging testing is not regionally available, a serum test (FIBROSpect II; Fibrometer; enhanced liver fibrosis [ELF], Fibrosure) can be used to confirm METAVIR F2 or greater but cannot be used for denial.~~<br><br>~~For results falling in a range (e.g. F1 to F2), fibrosis stage should be categorized as the higher F stage for the purpose of treatment, or require one additional, more specific test (per HERC AUROC values http://www.oregon.gov/OHA/HPA/CSI-HERC/Pages/Evidence-based-Reports-Blog.aspx?View=%7b2905450B-49B8-4A9B-AF17-5E1E03AB8B6B%7d&SelectedID=237) to be obtained to determine the stage of fibrosis. However, additional testing cannot be limited to biopsy. After one additional test, if a range still exists, the highest F score in the range will be used for determining coverage.~~ | **No:** Go to #8 |

| Approval Criteria | | |
|---|---|---|
| ~~8. Does the patient have one of the following extrahepatic manifestations of Hepatitis C?~~<br>~~a) Lymphoproliferative disease, including type 2 or 3 cryoglobulinemia with end-organ manifestations (i.e., leukocytoclastic vasculitis);~~ or<br>~~b) Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis;~~ or<br>~~c) Porphyria cutanea tarda or lichen planus~~<br>~~d) Lymphomas (B-cell non-Hodgkin lymphoma)~~<br>~~e)~~a) ~~Type 2 Diabetes~~ | ~~**Yes:** Go to #10~~ | ~~**No:** Go to #9~~ |
| ~~9. Is the patient in one of the following transplant settings:~~<br>~~a) Listed for a transplant and treatment is essential to prevent recurrent hepatitis C infection post-transplant;~~ or<br>~~b)~~a) ~~Post solid organ transplant?~~ | ~~**Yes:** Go to #10~~ | ~~**No:** Pass to RPh. Deny; medical appropriateness.~~ |
| ~~10. If METAVIR F4: Is the regimen prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist?~~ ~~**OR**~~<br>~~11.~~7.<br>~~If METAVIR F3:~~ Is the regimen prescribed by, OR is the patient in the process of establishing care with or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist? ~~**OR**~~<br><br>~~If METAVIR <~~F2: ~~The regimen does not need to be prescribed by or in consultation with a specialist.~~ | **Yes:** Go to #~~8~~11 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Forward to DMAP for further manual review to determine appropriateness of prescriber. |
| ~~12.~~8. Is there attestation that the patient and provider will comply with all case management interventions to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load? | **Yes**: Go to #~~9~~12 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| ~~13.~~9. Is the prescribed drug:<br>a) Elbasvir/grazoprevir for GT 1a infection; or<br>b) Daclatasvir + sofosbuvir for GT 3 infection? | **Yes**: Go to #1~~03~~ | **No:** Go to #114 |
| ~~14.~~10. Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #16?<br><br>Note: Baseline NS5A resistance testing is required. | **Yes:** Pass to RPh; deny for appropriateness | **No:** Go to #114<br><br>Document test and result. |
| ~~15.~~11. Is the prescribed regimen include a NS3/4a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir)? | **Yes:** Go to #1~~25~~ | **No:** Go to #1~~36~~ |
| ~~16.~~12. Does the patient have moderate-severe hepatic impairment (Child-Pugh B or Child-Pugh C)? | **Yes:** Pass to RPh; deny for appropriateness | **No:** Go to #1~~36~~ |
| ~~17.~~13. Is the prescribed regimen for the retreatment after failure of a DAA due to noncompliance or lost to follow-up? | **Yes:** Pass to RPh; Deny and refer to medical director for review | **No:** Go to #1~~47~~ |
| ~~18.~~14. Is the prescribed drug regimen a recommended regimen based on the patient's genotype, treatment status (retreatment or treatment naïve) and cirrhosis status (see **Table 1**)? | **Yes:** Approve for 8-16 weeks based on duration of treatment indicated for approved regimen | **No:** Pass to RPh. Deny; medical appropriateness. |